

May 10, 1966

Mr. O. J. Britton
Technical Development Department
The Pfaudler Company
Rochester, New York 14603

Dear Mr. Britton:

I have received a reply, after some delay, not from Dr. Arnold Lehman, to whom I wrote concerning your proposal, but from the Assistant Commissioner, Mr. J. K. Kirk. I send you, herewith a reproduction of the letter, from which you will see that the outlook is not favorable. I am not prepared, however, to accept this as a satisfactory answer to my question, and unless you instruct me to the contrary in dealing with your problem, in which, of course, your decision is final, I shall inquire further.

I shall be in Washington on two occasions within this and next month, and I'd like to pursue this matter further. It is entirely possible that what you have in mind will be an improvement over present process equipment in a number of situations involving food and beverages, and I would not like to have it dismissed on the basis of Mr. Kirks letter, without a hearing, and eventually a careful consideration of the adequacy of the coating in resisting the extraction of lead.

The reason I wrote Lehman was that I wanted a technical rather than an administrative answer. It now appears that he has removed himself from this area of policy, or that he has been removed from it, administratively. In either case it is too bad.

If you think I should drop this, so far as your people are concerned, I shall do so. But if you are willing for me to do so, I'll pursue it further with the idea of our determining, initially, the quality of your product, and of representing you, so far as these facts are concerned, in Washington. It is likely, I should say without knowing anything about the situation or Mr. Kirk, that Mr. Kirk has no knowledge of the extent to which we have dealt with matters of this type. I say this because of the tone of his letter, in which there is no indication of his recognition of our role in a number of situations of this type. I suspect that a direct interview might (one never knows what to expect of bureaucracy) have a different result.

I have made no reference to your company, nor shall I do so unless you wish me to do so. Moreover, I shall make no further move until you let me know your wishes.

Very truly yours,

RAK:wp
enclosure

Robert A. Kehoe, M.D.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

WASHINGTON, D.C. 20204

May 2, 1966

Robert A. Kehoe, M.D.
Kettering Laboratory
University of Cincinnati
Eden and Bethesda Avenues
Cincinnati, Ohio 45219

Dear Dr. Kehoe:

Dr. Lehman has asked that we reply to your letter of April 11 about the use of lead-containing materials on the inside of food processing and storage tanks.

Over the years we have had various problems involving lead as a food contact surface. Some years ago lead-bearing steels were under consideration for this use, but the data showed a definite lead uptake from the steel when in contact with food-type solvents and, in some cases, the food itself. We advised against its use. Then, as short a time as two years ago, we encountered some lead pigmented chinaware made in another country, and the lead uptake by the food was so high as to be dangerous.

Basically, our policy is opposed to any sanction of lead-containing surfaces to be used in contact with food. We do, of course, make a distinction between trace amounts of lead which may be an impurity. There is one exception to this rule and that involves the lead-tin solders used for cans and also in food processing equipment. There are three mitigating factors here:

1. The exposure is not to lead, but to a lead-tin solder in which case the tin has been shown to repress markedly the solubility of the lead even in highly acid foods;

2. The exposure is minimal, side seams in tin cans even if uncoated and the hole closure in evaporated milk cans -- and spots or joints in equipment;

3. A tremendous amount of data adduced by several investigators have demonstrated that the uptake of lead by food under these conditions is negligible and hence safe -- Clifford of FDA, Cheftel of France, and the War Production Board of the United States.

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It should be kept in mind that food contact surfaces are covered by the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, and in the instance of your client's proposal we believe there is little chance that our scientists could conclude that the proposal should be authorized under a food additive regulation.

Sincerely yours,



J. K. Kirk (202) 962-3012
Assistant Commissioner

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